

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/27239

## A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61K 39/02( 2006.01)

USPC: 424/190.1

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
U.S. : 424/190.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
MEDLINE, BIOSIS, HCAPLUS, EMBASE, DERWENT, PUBLISHED APPLICATIONS AND ISSUED PATENTS.

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/34771 A2 (TELFORD et al ) 02 May 2002 (02.05.2002), see pages 1411 and 3057. (only the relevant pages provided)	1-7 and 17-24
X	LARSSON et al. Protection against experimental infection with group B streptococcus by immunization with a bivalent protein vaccine. Vaccine. February 1999, Vol. 17, No. 5, pages 454-458.	1-7 and 17-24

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

### \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

21 May 2008 (21.05.2008)

Date of mailing of the international search report

25 AUG 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Authorized officer

PADMA v. BASKAR

Telephone No. 571-272-1600

*J. Roberts for*

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### Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: 1-7 and 17-24
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

- Remark on Protest**
- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

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### BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

1. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim 1 -7 (in part) drawn to an immunogenic composition comprising a purified Group B Streptococcus adhesion island polypeptide.

Further species election to one composition comprising GBS AI -1 or GBS AI -2 required (see paragraph # 3).

Group II, claims 8-16 (in part) drawn to an immunogenic composition comprising a purified gram positive adhesion island polypeptide.

Further species election to one composition comprising one bacteria and one GAS AI -1 ,GAS AI -2,GAS AI -3 and GAS AI -4 required (see paragraph # 3).

Group III, claims 17-24 (in part) drawn to an immunogenic composition comprising a first and second purified Group B Streptococcus adhesion island polypeptide.

Further species election to one combination of first and second polypeptide (see paragraph # 3).

Group IV, claims 25-34 (in part) drawn to an immunogenic composition comprising a first and second gram positive GAS AI -adhesion island polypeptide.

Further species election to one combination of first and second polypeptide (see paragraph # 3).

Group V, claims 35-39 and 40 (in part) drawn to a modified gram positive bacterium and a method of manufacturing adhesion island antigen

Further species election to one modified gram positive bacterium required (see paragraph # 3).

Group I is directed to an immunogenic composition comprising polypeptide GBS AI -1 or GBS AI -2 whereas Group II is drawn to immunogenic composition comprising gram positive bacterial adhesion polypeptides GAS AI -1 , GAS AI -2 , GAS AI -3 and GAS AI -4 . These inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 because these two compositions do not share a common structure ,property and function as group I contains GBS polypeptide where as group II comprises GAS polypeptides . Group III and Group IV are also drawn to compositions as group III comprises combination of two polypeptides from GBS that shares no common structure ,property and function with Group IV as it comprises GAS polypeptide and thus do not share a single inventive concept. Thus these inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 Group V is drawn to a modified bacterium from GBS , GAS and non-pathogenic gram positive bacterium comprising expressing polypeptide GBS- AI -1or GBS-AI-2 and not share a single inventive concept from other four groups as the composition contains polypeptides which does not share a common structure, property and function.



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2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

3 Group I species: GBS AI -1 80, 104, 52, 59, 67, 150, 01521, 01523, 01524 or GBS AI -2

Group II species: GAS AI -1, GAS AI -2, GAS AI -3 and GAS AI -4.

Group III species: Any combination of first and second polypeptide from GBS AI -1 80, 104, 52, 59, 67, 150, 01521, 01523, 01524, GBS AI -2.

Group IV species: Any combination of first and second polypeptide from GAS AI -1, GAS AI -2, GAS AI -3 and GAS AI -4

Group V species: Modified gram-positive bacterium or non pathogenic bacterium expressing GBS AI -1 80, 104, 52, 59, 67, 150, 01521, 01523, 01524, GBS AI -2, GAS AI -1, GAS AI -2, GAS AI -3 and GAS AI -4

The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of linking groups appears to be that they are all related to immunogenic compositions comprising adhesion peptides methods of making adhesion peptide.

However, Beckmann et al Infection and Immunity, June 2002, p. 2869-2876, Vol. 70, No. 6 disclose an immunogenic composition comprising adhesion oligomeric polypeptide ( see page 2871, left column last paragraph through right column and figure 3) As this polypeptide binds to fibrinogen it is an adhesion immunogen. Therefore, the technical feature of linking groups 1-5 does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

The special technical feature of Groups 1-5 is considered to be immunogenic compositions comprising polypeptides that share no common structure, property and function and thus do not share the same or a corresponding technical feature.

Accordingly, Groups 1-5 are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The claimed species GBS AI -1 80, 104, 52, 59, 67, 150, 01521, 01523, 01524, GBS AI -2; GAS AI -1, GAS AI -2, GAS AI -3 and GAS AI -4 have no common structure and thus are not linked by the same or a corresponding special technical feature so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among species.